

510(k) Summary of Safety and Effectiveness:

AUG 16 2012

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068
Contact: Charlemagne Chua, Manager Regulatory Affairs
Telephone No.: (714) 730-5000

Device Proprietary Name: DIAGNOSTIC ULTRASOUND SYSTEM
APLIO 500 MODEL TUS-A500 Version 2.1
APLIO 400 MODEL TUS-A400 Version 2.1
APLIO 300 MODEL TUS-A300 Version 2.1

Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN
[Fed.Reg.No.:892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO
[Fed.Reg.No.:892.1560]
Diagnostic Ultrasonic Transducer – Product Code: 90-ITX
[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

- 1) Toshiba DIAGNOSTIC ULTRASOUND SYSTEM APLIO 500 MODEL TUS-A500 / APLIO 400 MODEL TUS-A400 / APLIO 300 MODEL TUS-A300 V2.0 ; 510(k) control number K110870

Device Description:

The DIAGNOSTIC ULTRASOUND SYSTEM APLIO 500 MODEL TUS-A500, APLIO 400 MODEL TUS-A400 and APLIO 300 MODEL TUS-A300 are mobile system. These systems are Track 3 devices that employ a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Indications for Use:

The DIAGNOSTIC ULTRASOUND SYSTEM APLIO 500 MODEL TUS-A500, APLIO 400 MODEL TUS-A400 and APLIO 300 MODEL TUS-A300 is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, and musculoskeletal (both conventional and superficial).

Declaration of Conformity

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC60601-2-37 (applicable portions), IEC 62304 (applicable portion) and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

Standards form:

Please see the attached standard form of the IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37 and IEC 62304.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Toshiba Medical Systems Corporation, Japan
% Mr. Charlemagne Chua
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780-2068

AUG 16 2012

Re: K121422

Trade/Device Name: Aplio™ 500/400/300 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 13, 2012
Received: July 16, 2012

Dear Mr. Chua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio™ 500/400/300 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>PST-25BT</u>	<u>PVT-661VT</u>	<u>PVT-770RT</u>	<u>PLT-1204BT</u>
<u>PST-30BT</u>	<u>PVT-674BT</u>	<u>PLT-604AT</u>	<u>PLT-1204BX</u>
<u>PST-50BT</u>	<u>PVT-675MV</u>	<u>PLT-704AT</u>	<u>PLT-1204MV</u>
<u>PST-65AT</u>	<u>PVT-681MV</u>	<u>PLT-704SBT</u>	<u>PET-508MA</u>
<u>PVT-375BT</u>	<u>PVT-712BT</u>	<u>PLT-705BTF</u>	<u>PET-510MB</u>
<u>PVT-375MV</u>	<u>PVT-745BTF</u>	<u>PVT-705BTH</u>	<u>PET-512MC</u>
<u>PVT-382BT</u>	<u>PVT-745BTH</u>	<u>PLT-805AT</u>	<u>PC-20M</u>
<u>PVT-382MV</u>	<u>PVT-745BTV</u>	<u>PLT-1202S</u>	<u>PC-50M</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

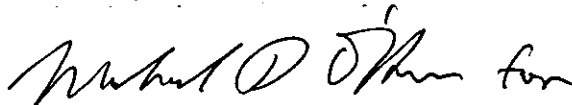
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): _____

Device Name:

Aplio™ 500 /400/300 Diagnostic Ultrasound System

Indications for Use:

The DIAGNOSTIC ULTRASOUND SYSTEM APLIO 500 MODEL TUS-A500, APLIO 400 MODEL TUS-A400 and APLIO 300 MODEL TUS-A300 is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, and musculoskeletal (both conventional and superficial).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



(Division Sign-Off)

Division of Radiological Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number

K121422

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P	P	P	2	P	P	P		P	5,7
Abdominal	P	P	P	P	P	2,3	P	P	P		P	5,7,12
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	2,3	P	P	P		P	5,7,12
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,11
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
Trans-rectal	P	P	P		P	2	P	P	P		P	4,5,7,11
Trans-vaginal	P	P	P		P	2	P	P	P		P	4,5,7
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P	P	P	2	P	P	P			4,5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC


Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121422

Prescription Use Only (Per 21 CFR801.109)

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

Q100

510k

MAY 2012

A-2

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

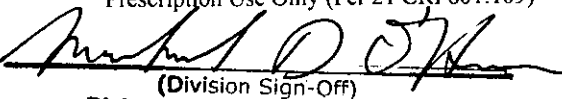
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
510k K121422

A-3

MAY 2012

510(k): APLIO 500/400/300, v2.1
Page 191 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PST-50BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	E	E	E	E	E	3	E	E	E			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	E	E	E	E	E	3	E	E	E			
Small Organ (Specify) (1)												
Neonatal Cephalic	E	E	E	E	E	3	E	E	E			
Adult Cephalic	E	E	E	E	E	3	E	E	E			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	E	E	E	E	E	3	E	E	E	E		4,13
Cardiac Pediatric	E	E	E	E	E	3	E	E	E	E		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K090158

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)


Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
510k K121432
MAY 2012

A-4

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	E	E	E	E	E	3	E	E	E			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	E	E	E	E	E	3	E	E	E			
Small Organ (Specify) (1)												
Neonatal Cephalic	E	E	E	E	E	3	E	E	E			
Adult Cephalic	E	E	E	E	E	3	E	E	E			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	E	E	E	E	E	3	E	E	E	E		4,13
Cardiac Pediatric	E	E	E	E	E	3	E	E	E	E		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

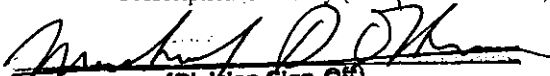
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
K121422
MAY 2012

A-5

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			5, 7
Abdominal	P	P	P		P	2	P	P	P			5, 7, 11, 12
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7, 12
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)


Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
Q100
K101400
510k MAY 2012

A-6

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-375MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P		N	5,7,8,9,10
Abdominal	P	P	P		P	2	P	P	P		N	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		N	5,7,8,9,10
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

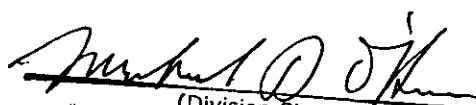
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
MAY 2012
510k K121422

A-7

System: Aplio 300, Aplio 400, Aplio 500 v2.1
Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			5, 7
Abdominal	P	P	P		P	2	P	P	P			5, 7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

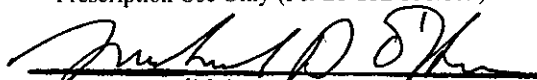
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
MAY 2012 K121422

A-8

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1
Transducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P		P	5, 7, 9
Abdominal	P	P	P		P	2	P	P	P		P	5, 7, 9
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		P	5, 7, 9
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

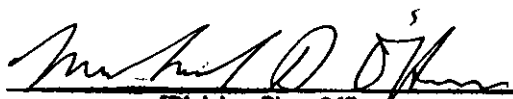
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)



(Division Sign-Off)
Division of Radiological Devices

A-9

MAY 2012



510(k): APLIO 500/400/300, v2.1
Page 197 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P			4,5,7,11
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,7,11
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

A-10

510k
MAY 2012

510(k): APLIO 500/400/300, v2.1
Page 198 of 3006

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			5,7
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5,7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

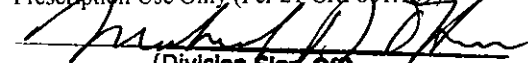
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)



Division of Radiological Devices

A-11

MAY 2012

K121422

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-675MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Abdominal	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

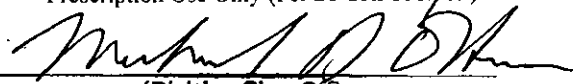
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

A-12

510(k)
MAY 2012

K121422

510(k): APLIO 500/400/300, v2.1
Page 200 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1)TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-681MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P		P	4,5,7,9,11
Trans-vaginal	P	P	P		P	2	P	P	P		P	4,5,7,9,11
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

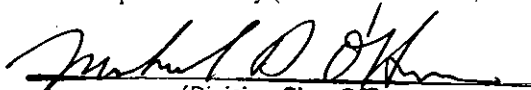
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
K121422

A-13

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PVT-712BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P		P	5,7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5,7
Small Organ (Specify) (1)												
Neonatal Cephalic	P	P	P		P	2	P	P	P			5,7
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

A-14

510k
MAY 2012

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PVT-745BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	E	E	E		E	2	E	E	E			5,7
Intra-operative (Abdominal)	E	E	E		E	2	E	E	E			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	E	E	E		E	2	E	E	E			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: None

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)

[Signature]
 (Division Sign-Off)
 Division of Radiological Devices
 OIVD
 K121422

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PVT-745BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	E	E	E		E	2	E	E	E			5,7
Intra-operative (Abdominal)	E	E	E		E	2	E	E	E			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	E	E	E		E	2	E	E	E			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: None

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)
Division of Radiological Devices
510k *121422*

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PVT-745BTV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

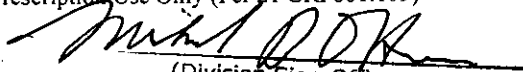
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

A-17

MAY 2012

K121432

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-770RT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	E	E	E		E	2	E	E	E			4,5,7,11
Trans-vaginal	E	E	E		E	2	E	E	E			4,5,7,11
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

JK

6121422

A-18

MAY 2012

510(k): APLIO 500/400/300, v2.1
Page 206 of 3006

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PLT-604AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	E	E	E		E	2	E	E	E			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	E	E	E		E	2	E	E	E			5,7
Musculo-skeletal (Superficial)	E	E	E		E	2	E	E	E			5,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	E	E	E		E	2	E	E	E			5,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)
Division of Radiological Devices
MAY 2012 6121422

A-19

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	E	E	E		E	2	E	E	E			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	E	E	E		E	2	E	E	E			5,7
Musculo-skeletal (Superficial)	E	E	E		E	2	E	E	E			5,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	E	E	E		E	2	E	E	E			5,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)
Division of Radiological Devices
MAY 2012 K121422

A-20

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			5,7
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			5,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

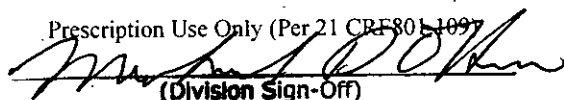
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.1097)



(Division Sign-Off)

Division of Radiological Devices

A-21

MAY 2012

K121422

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PLT-705BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	E	E	E		E	2	E	E	E			5,7
Intra-operative (Abdominal)	E	E	E		E	2	E	E	E			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)

[Signature]
 (Division Sign-Off)
 Division of Radiological Devices
 MAY 2012 K121432

A-22

System: Aplio 300, Aplio 400, Aplio 500 v2.1
Transducer: PVT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	E	E	E		E	2	E	E	E			5,7
Intra-operative (Abdominal)	E	E	E		E	2	E	E	E			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)



(Division Sign-Off)

Division of Radiological Devices

A-23

MAY 2019

K121432

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,6,7,11
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			5,6,7,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

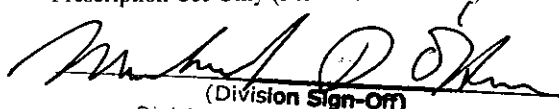
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

510k

K121482

A-24

MAY 2012

510(k): APLIO 500/400/300, v2.1
Page 212 of 3006

System: Aplio 300, Aplio 400, Aplio 500 v2.1Transducer: PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)	P	P	P		P	2	P		P			4,5,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P		P			4,5,11
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P		P			4,5,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P		P			4,5,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N		N			4,5,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

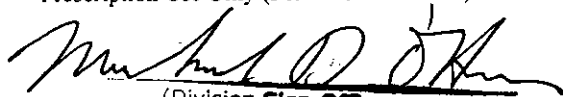
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
MAY 2012 K121432

A-25

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6,7,11
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N			4,5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

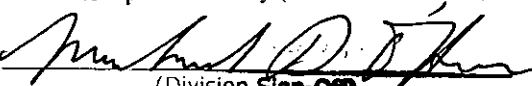
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
K121402

A-26

510(k)
MAY 2012

510(k): APLIO 500/400/300, v2.1
Page 214 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 500 v2.1

Transducer: PLT-1204BX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			5,7
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			5,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

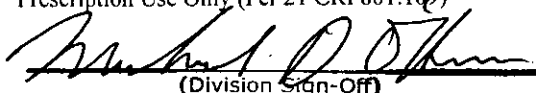
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

A-27

510k
MAY 2012

510(k): APLIO 500/400/300, v2.1
Page 215 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PLT-1204MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

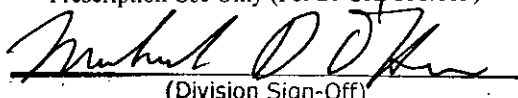
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

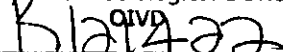
Prescription Use Only (Per 21 CFR 801.109)


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Division of Radiological Devices

A-28

510(k) 2012



510(k): APLIO 500/400/300, v2.1
Page 216 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PET-508MA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	E	E	E	E	E	3	E					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: None

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

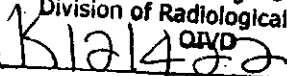
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Division of Radiological Devices

A-29

MAY 2002



510(k): APLIO 500/400/300, v2.1
Page 217 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

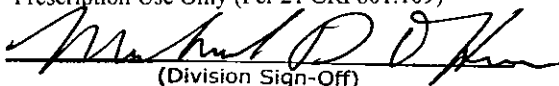
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

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Division of Radiological Devices

510k

MAY 2012

A-30

510(k): APLIO 500/400/300, v2.1
Page 218 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PET-512MC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	E	E	E	E	E	3	E					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103629

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

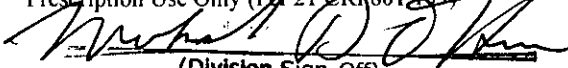
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

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Division of Radiological Devices
K121432

A-31

MAY 2012

510(k): APLIO 500/400/300, v2.1
Page 219 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult				P								
Cardiac Pediatric				P								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				P								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

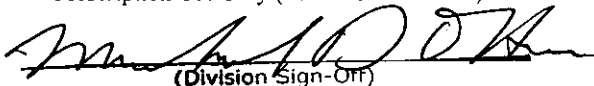
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

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Division of Radiological Devices

A-32

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MAY 2012

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510(k): APLIO 500/400/300, v2.1
Page 220 of 3006

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™500(v2.1) TUS-A500 Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PC-50M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult				P								
Cardiac Pediatric				P								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				P								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

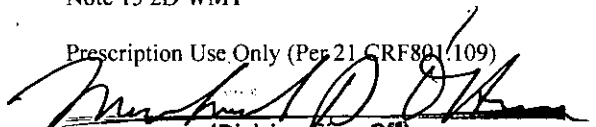
Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CFR 801.109)


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Division of Radiological Devices
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MAY 2012

A-33